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April 23, 2004

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Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

Art Unit 1636

Re: U.S. Utility Patent Application
Application No. 09/705,940; Filed: November 6, 2000
For: **Dry Powder Cells and Cell Culture Reagents and Methods of
Production Thereof**
Inventors: FIKE *et al.*
Our Ref: 0942.4290006/RWE/FRC

Sir:

Transmitted herewith for appropriate action are the following documents:

1. Fee Transmittal Form (PTO/SB/17);
2. Petition for Extension of Time Under 37 C.F.R. § 1.136(a)(1);
3. Reply Under 37 C.F.R. § 1.111;
4. PTO Credit Card Form (PTO-2038) in the amount of **\$110.00** to cover the extension of time fee; and
5. One (1) return postcard.

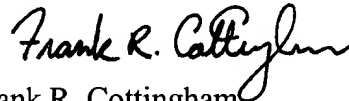
It is respectfully requested that the attached postcard be stamped with the date of filing of these documents, and that it be returned to our courier. In the event that extensions of time are necessary to prevent abandonment of this patent application, then such extensions of time are hereby petitioned.

Commissioner for Patents
April 23, 2004
Page 2

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

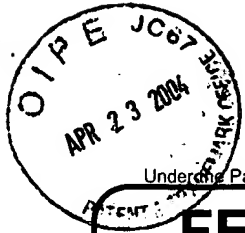
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FRC/shr
Encls.

SKGF_256706.1



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FEE TRANSMITTAL for FY 2004

Effective 10/01/2003. Patent fees are subject to annual revision.

☐ Applicant claims small entity status. See 37 CFR 1.27

TOTAL AMOUNT OF PAYMENT (\$) 110.00

Complete if Known

Application Number	09/705,940
Filing Date	November 6, 2000
First Named Inventor	FIKE et al.
Examiner Name	Lambertson, D.
Art Unit	1636
Attorney Docket No.	0942.4290006/RWE/FRC

METHOD OF PAYMENT (check all that apply)

☐ Check ☒ Credit card ☐ Money Order ☒ Other** ☐ None

☐ **Charge any deficiencies or credit any overpayments in Deposit Account: the fees to Deposit Acct. No. 19-0036

Deposit Account Number: 19-0036
Deposit Account Name: Sterne Kessler, Goldstein & Fox P.L.L.C.

The Director is authorized to: (check all that apply)

☒ Charge fee(s) indicated below ☒ Credit any overpayments

☒ Charge any additional fee(s) or any underpayment of fee(s)

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FEE CALCULATION

1. BASIC FILING FEE

Large Entity	Small Entity	Fee Description	Fee Paid
Fee Code (\$)	Fee Code (\$)		
1001 770	2001 385	Utility filing fee	
1002 340	2002 170	Design filing fee	
1003 530	2003 265	Plant filing fee	
1004 770	2004 385	Reissue filing fee	
1005 160	2005 80	Provisional filing fee	
SUBTOTAL (1)			(\$) 0.00

2. EXTRA CLAIM FEES FOR UTILITY AND REISSUE

Total Claims	Extra Claims	Fee from below	Fee Paid
Independent Claims	**=	X	
Multiple Dependent	**=	X	

Large Entity	Small Entity	Fee Description	Fee Paid
Fee Code (\$)	Fee Code (\$)		
1202 18	2202 9	Claims in excess of 20	
1201 86	2201 43	Independent claims in excess of 3	
1203 290	2203 145	Multiple dependent claim, if not paid	
1204 86	2204 43	** Reissue independent claims over original patent	
1205 18	2205 9	** Reissue claims in excess of 20 and over original patent	
SUBTOTAL (2)			(\$) 0.00

**or number previously paid, if greater; For Reissues, see above

FEE CALCULATION (continued)

3. ADDITIONAL FEES

Large Entity	Small Entity	Fee Description	Fee Paid
Fee Code (\$)	Fee Code (\$)		
1051 130	2051 65	Surcharge - late filing fee or oath	
1052 50	2052 25	Surcharge - late provisional filing fee or cover sheet	
1053 130	1053 130	Non-English specification	
1812 2,520	1812 2,520	For filing a request for <i>ex parte</i> reexamination	
1804 920*	1804 920*	Requesting publication of SIR prior to Examiner action	
1805 1,840*	1805 1,840*	Requesting publication of SIR after Examiner action	
1251 110	2251 55	Extension for reply within first month	110.00
1252 420	2252 210	Extension for reply within second month	
1253 950	2253 475	Extension for reply within third month	
1254 1,480	2254 740	Extension for reply within fourth month	
1255 2,010	2255 1,005	Extension for reply within fifth month	
1401 330	2401 165	Notice of Appeal	
1402 330	2402 165	Filing a brief in support of an appeal	
1403 290	2403 145	Request for oral hearing	
1451 1,510	1451 1,510	Petition to institute a public use proceeding	
1452 110	2452 55	Petition to revive - unavoidable	
1453 1,330	2453 665	Petition to revive - unintentional	
1501 1,330	2501 665	Utility issue fee (or reissue)	
1502 480	2502 240	Design issue fee	
1503 640	2503 320	Plant issue fee	
1460 130	1460 130	Petitions to the Commissioner	
1807 50	1807 50	Processing fee under 37 CFR 1.17(q)	
1806 180	1806 180	Submission of Information Disclosure Stmt	
8021 40	8021 40	Recording each patent assignment per property (times number of properties)	
1809 770	2809 385	Filing a submission after final rejection (37 CFR 1.129(a))	
1810 770	2810 385	For each additional invention to be examined (37 CFR 1.129(b))	
1801 770	2801 385	Request for Continued Examination (RCE)	
1802 900	1802 900	Request for expedited examination of a design application	
Other fee (specify)			
*Reduced by Basic Filing Fee Paid			
SUBTOTAL (3)			(\$) 110.00

SUBMITTED BY

(Complete (if applicable))

Name (Print/Type)	Frank R. Cottingham	Registration No. (Attorney/Agent)	50.437	Telephone	(202) 371-2600
Signature	Frank R. Cottingham	Date	APR. 23, 2004		

WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

This collection of information is required by 37 CFR 1.17 and 1.27. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS.

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

FIKE *et al.*

Appl. No. 09/705,940

Filed: November 6, 2000

For: **Dry Powder Cells and Cell
Culture Reagents and Methods of
Production Thereof**

Confirmation No.: 7464

Art Unit: 1636

Examiner: Lambertson, D.

Atty. Docket: 0942.4290006/RWE/FRC

Reply Under 37 C.F.R. § 1.111

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

In reply to the Office Action dated **December 23, 2003**, (PTO Prosecution File Wrapper Paper No. 15), Applicants submit the following Remarks.

It is not believed that extensions of time or fees for net addition of claims are required beyond those that may otherwise be provided for in documents accompanying this paper. However, if additional extensions of time are necessary to prevent abandonment of this application, then such extensions of time are hereby petitioned under 37 C.F.R. § 1.136(a), and any fees required therefor (including fees for net addition of claims) are hereby authorized to be charged to our Deposit Account No. 19-0036.

Remarks

Reconsideration of this Application is respectfully requested.

Claims 1-10, 15, 16, 18-29, 31-34 and 36-44 are pending in the application, with claim 1 being the sole independent claim.

Based on the following remarks, Applicants respectfully request that the Examiner reconsider all outstanding rejections and that they be withdrawn.

Claim Rejections Under 35 U.S.C. § 102

Claims 1-10, 15, 16, 18-29, 31-34 and 36-44 were rejected under 35 U.S.C. § 102(b) as being anticipated by WO 98/36051. *See* Paper No. 15, page 2. Applicants respectfully traverse this rejection.

Under 35 USC § 102, a claim can only be anticipated if every element in the claim is expressly or inherently disclosed in a single prior art reference. *See Kalman v. Kimberly Clark Corp.*, 713 F.2d 760, 771 (Fed. Cir. 1983), *cert. denied*, 465 U.S. 1026 (1984). As noted in Applicants' Amendment and Reply Under 37 C.F.R. § 1.116, filed on May 12, 2003, WO 98/36051 does not disclose all of the elements of any of the claims. More specifically, WO 98/36051 does not disclose determining the ratio of pH-opposing forms of buffer salts required to be added to a powdered culture medium to automatically provide a desired pH upon reconstitution of the powder with a solvent.

In response to Applicants' remarks presented in the previous reply, the Examiner has recast the rejection as one of inherent anticipation. *See* Paper No. 15, page 4. The logic underlying the Examiner's assertion of inherent anticipation, however, is based on a misunderstanding of the teachings of WO 98/36051, and therefore cannot support a rejection under 35 U.S.C. § 102.

The Examiner stated that:

Fike clearly teaches the use of one or more buffer salts in the production of a nutritive medium (see for example page 20, lines 3-4). Fike further teaches that this nutritive media can be formulated to produce a powdered medium that obviates the need for the subsequent addition of a pH-adjusting agent following reconstitution, thereby producing an "automatically pH-adjusting medium" which avoids the error-prone steps of adding buffer or a pH-adjusting agent to the medium after it is reconstituted (see for example page 20, lines 13-21).

Paper No. 15, page 3. In light of the foregoing statements, the Examiner asserted that: "[i]n order to avoid the use of a pH-adjusting agent, one would necessarily need to achieve the desired pH through an alternative mechanism." *See* Paper No. 15, pages 3-4. This statement, which forms the basis of the inherency argument, is inaccurate and does not logically follow from the portion of WO 98/36051 cited by the Examiner.

The portion of WO 98/36051 cited by the Examiner does not in any way suggest "avoid[ing] the use of a pH-adjusting agent;" in fact, it specifically requires the use of a pH-adjusting agent (either HCl or NaOH). The portion of WO 98/3605 cited by the Examiner indicates that pH-adjusting agents such as HCl or NaOH are added to powdered nutritive media *so that pH-adjusting agents do not have to be added again after the powder is reconstituted with a solvent (i.e., "obviat[ing] the time consuming and error-prone steps of*

adding buffer(s) to the medium *after reconstitution* and adjusting the pH of the medium *after dissolution* of the buffer(s).") See WO 98/36051, page 20, lines 19-21 (emphasis added).

In other words, according to WO 98/36051, since the pH-adjusting agent is added when the medium is in a powdered form, no pH-adjusting agents are needed when the medium is reconstituted to a liquid form. The actual language of WO 98/36051, which makes this point entirely clear, is as follows:

In a related aspect, a pH-adjusting agent such as an acid (*e.g.*, HCl) or a base (*e.g.*, NaOH) may be added to a powdered nutritive medium, which may contain one or more buffer salts (such as sodium bicarbonate), by agglomeration of the pH-adjusting agent into the powdered nutritive medium in a fluid bed apparatus, by spray-drying the pH-adjusting agent onto the powdered or agglomerated nutritive medium, or by a combination thereof; *this approach obviates the subsequent addition of a pH-adjusting agent after reconstitution of the powdered medium.* Thus, the invention provides a powdered nutritive culture medium useful in cultivation or growth of cells *in vitro* that, upon reconstitution with a solvent (*e.g.*, water or serum), has a pH that is optimal for the support of cell cultivation or growth without a need for adjustment of the pH of the liquid medium. This type of medium, defined herein as "automatically pH-adjusting medium," therefore obviates the time-consuming and error-prone steps of adding buffer(s) to the medium after reconstitution and adjusting the pH of the medium after dissolution of the buffers.

See WO 98/36051, page 20, lines 3-21 (emphasis added). The "approach" referred to in the above-quoted language, which "obviates the subsequent addition of a pH-adjusting agent after reconstitution of the powdered medium," is the addition of HCl or NaOH to the dry powdered medium. Nowhere in WO 98/36051 is it indicated or implied that pH-adjusting agents are altogether avoided, as asserted by the Examiner. This is an important point

because the inherency argument put forth by the Examiner necessarily depends on this erroneous interpretation of WO 98/36051.

According to the Examiner, "in order to avoid the use of a pH-adjusting agent in the formulation of an 'automatically pH-adjusting medium,' Fike *must inherently* teach the use of pH-opposing forms of buffer salts, and the determination of the ratios of these buffer salts to give a desired pH." See Paper No. 15, page 4 (emphasis in original). The Examiner has cited Gomori, *Methods Enzymol.* 16:138-146 (1955), to support this assertion. There is nothing in WO 98/36051, however, to suggest avoiding the use of pH-adjusting agents. In fact, according to WO 98/36051, the production of automatically pH-adjusting media is achieved *specifically* by adding pH-adjusting agents such as HCl or NaOH to the dry powdered media. Contrary to the Examiner's assertion, no "alternative mechanism," see Paper No. 15, page 4, would have been needed to achieve the desired pH.

A rejection based on inherent anticipation requires evidence that the allegedly inherent characteristic is *necessarily* present in the cited reference. *In re Schreiber*, 128 F.3d 1473, 1477, 44 USPQ2d 1429, 1431 (Fed. Cir. 1997). Since the automatically pH-adjusting media of WO 98/36051 is achieved by using HCl or NaOH, there is no need in WO 98/36051 for pH-opposing forms of buffer salts. Therefore, pH-opposing forms of buffer salts cannot *necessarily* be present in the disclosure. No evidence or logically sound arguments have been presented which indicate that pH-opposing forms of buffer salts are *necessarily present* in the disclosure of WO 98/36051. Thus, a rejection based on inherent anticipation has not been established. Applicants therefore respectfully request that the rejection under § 102 be reconsidered and withdrawn.

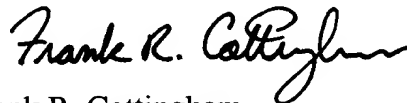
Conclusion

All of the stated grounds of rejection have been properly traversed, accommodated, or rendered moot. Applicants therefore respectfully request that the Examiner reconsider the presently outstanding rejection and that it be withdrawn. Applicants believe that a full and complete reply has been made to the outstanding Office Action and, as such, the present application is in condition for allowance. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

Prompt and favorable consideration of this Reply is respectfully requested.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.



Frank R. Cottingham
Attorney for Applicants
Registration No. 50,437

Date: APR. 23, 2004

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